

REMARKS

Upon entry of the present reply, claims 1-16 and 20-31 will remain pending.

Reconsideration of the rejections and allowance of the application in view of the following remarks are respectfully requested.

Information Disclosure Statement

Applicant expresses appreciation for the Examiner's confirmation of consideration of Applicant's Information Disclosure Statements, filed October 26, 2006, by including initialed copies of the Forms PTO-1449 with the Office Action.

Applicant notes that the Examiner has crossed through Application No. 10/582,079 on the forms even though its published PCT application, i.e., WO 2005/058264 has been initialed as having been considered. The Office Action does not explain why the application is crossed through, and the Examiner is requested to confirm consideration of this application, because its citation is in compliance with 37 C.F.R. 1.98.

Still further, Applicant notes that the U.S. application has published as US 2007/0190086 A1.

Accordingly, Applicant has included both the application and its publication on the Form PTO-1449 submitted with the Supplemental Information Disclosure Statement filed on even date herewith, and the Examiner is requested to include an initialed copy of the form with the next communication from the Patent and Trademark Office.

Renumbering Of Claims

Applicant expresses appreciation for the indication in the Office Action that the claims have been renumbered so that the second renumbered claim 30 is presently claim 31 to correct an error in claim numbering in the Supplemental Preliminary Amendment.

Response To Rejections

The following rejections are set forth in the Office Action.

(a) Claims 1-11, 13-16 and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0072841 A1 to Rajaiah et al. (hereinafter "Rajaiah").

(b) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0072841 A1 to Rajaiah in view of Gibbs et al. (hereinafter "Gibbs"), International Journal of Food Sciences and Nutrition 1999.

Applicants submit that the rejections based upon Rajaiah, either alone or in view of Gibbs, are without appropriate basis, and should be withdrawn at least for the reasons set forth below.

Applicants' independent claim 1 is directed to a solid, oral tooth whitening composition comprising more than 75% by weight of solid materials, said composition comprising:

- (a) a chewing gum or confectionary base;
- (b) chewing gum or confectionary additives; and
- (c) a tooth whitening agent comprising calcium pyrophosphate present in an amount of between 0.5% and 9% by weight of the composition, excluding any coating compositions.

As recognized in the rejections, Rajaiah does not teach such a composition. Instead, the rejections contend that, despite the fact that one must "pick and choose" from different lists of

components throughout the reference, that it would have been obvious in a self-evident manner to have selected, for the chewing gum/confectionary composition of Rajaiah, calcium pyrophosphate as well as sugar-free sweeteners, flavors, urea, vitamin C, and sodium bicarbonate, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners. Moreover, the rejections assert that the adjustment of particular conventional working conditions of the composition of Rajaiah is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Applicant submits that the rejections are without sufficient basis, because the rejections do not indicate how Rajaiah is being modified, but merely make ambiguous assertions. For example, the rejections contend that the claimed subject matter is “obvious in a self-evident manner” in view of some asserted “basic principle of patent prosecution”. However, the rejections do not indicate why one having ordinary skill in the art would have picked and chosen components disclosed in Rajaiah to arrive at Applicant’s recited subject matter. This is especially the situation when there is no indication in the rejections what routine optimization would be performed and/or why one having ordinary skill in the art would manipulate the composition disclosed by Rajaiah to arrive at the claimed subject matter.

For example, Applicant submits that Rajaiah discloses chewing gum formulations comprising two components; a polybutene component and a chewing gum component [0009]. The polybutene component may comprise 50-90% of the composition [0024], the remainder being the “chewing gum component”. The polybutene component of the composition according to Rajaiah is a flowable liquid [0026], and thus not a “solid component”. Thus, in order for the

skilled person to arrive at the claimed subject matter starting from Rajaiah, in addition to “picking and choosing” the most suitable abrasive in the most preferred range, would also need to change the polybutene component of Rajaiah, which is an essential part of the composition disclosed by Rajaiah. Thus, to arrive at Applicant’s claimed subject matter would require that the desired composition of Rajaiah including the polybutene component be essentially destroyed to arrive at the claimed subject matter. The rejections have not established any motivation and/or any reason why one having ordinary skill in the art would, in effect, attempt to modify an what should be considered to be an essential component of the composition of Rajaiah to arrive at Applicant’s claimed subject matter. While Applicant’s claims do not exclude the presence of polybutene, one having ordinary skill in the art would not have modified Rajaiah to arrive at the composition recited in Applicant’s independent claim 1, and further defined in the dependent claims.

Further expanding upon the deficiencies of Rajaiah, Rajaiah discloses in [0059] typical abrasive polishing materials as including “silica gels and precipitates; aluminas; water insoluble phosphates (including orthophosphates, polymetaphosphates, and pyrophosphates); and mixtures thereof”. In [0059], Rajaiah further discloses specific examples of abrasives as including dicalcium orthophosphate dihydrate, calcium pyrophosphate, tricalcium phosphate, calcium polymetaphosphate, insoluble sodium polymetaphosphate, hydrated alumina, beta calcium pyrophosphate, calcium carbonate, and resinous abrasive materials such as particulate condensation products of urea and formaldehyde and melamine urea formaldehyde. Mixtures of abrasives may also be used.

In [0059], Rajaiah further discloses that: "The abrasive in the chewing gum compositions is generally from about 1% to about 70%, in one embodiment from about 5% to about 50%, by weight of the chewing gum or confection component."

Rajaiah does not disclose a whitening effect of the abrasive and Rajaiah does not contain any teaching or suggestion as to the particular selection of calcium pyrophosphate among several other abrasives for any purpose, let alone as an abrasive having a superior whitening effect. Further, Rajaiah does not contain any teaching or suggestion as to the particular selection of the preferred range of 0.5% - 9% calcium pyrophosphate on the basis of a proposed usable range of abrasive of 1-70%, an embodiment from about 5% to about 50%, of the solid oral compositions.

Rajaiah does not disclose the whitening effect of the abrasive. Consequently, there is no teaching or suggestion to arrive at Applicant's claimed subject matter in Rajaiah .

Rajaiah does not disclose the specific features of the present invention and therefore does not disclose the solution of the present invention.

The rejections of record do point to any disclosure of Rajaiah, or any other document, that would lead one having ordinary skill in the art to arrive at the recited tooth whitening agent comprising calcium pyrophosphate in an amount of 0.5% - 9 % as recited in Applicant's independent claim 1. Rajaiah merely discloses the possibility of adding to a chewing gum calcium pyrophosphate as one abrasive among a myriad of other possible abrasives, with the abrasives being proposed to be applied in a range of 1-70% of the solid oral compositions.

Applicant further notes that calcium pyrophosphate, according to Rajaiah is placed as one among several abrasives [0059], though Rajaiah additionally teaches the possibility of adding whitening substances [0039] to solid oral compositions.

Calcium pyrophosphate is not mentioned among the preferred whitening agents mentioned in [0039] in Rajaiah. There are no teaching or suggestion in Rajaiah as to any particular suitability of calcium pyrophosphate as a whitening agent, and especially there is no teaching or suggestion in Rajaiah to the particular suitability of calcium pyrophosphate over other abrasives as a whitening agent.

Moreover, the Examiner's attention is directed to the experiments disclosed in Applicant's specification. Prior art compositions comprising different concentrations of calcium pyrophosphate and calcium carbonate, respectively, have been tested, showing the superiority of a particular abrasive in a particular range for a particular purpose. Accordingly, the present application contains experimental data showing that calcium pyrophosphate is superior for whitening purposes to the commonly used calcium carbonate when formulated in chewing gum compositions (see e.g. table 1, page 16), and that calcium pyrophosphate is superior in inhibiting further discoloration of teeth (see e.g. table 2, page 18).

Therefore, for at least the reasons set forth above, the composition recited in Applicant's independent claim 1 is not taught or suggest by Rajaiah.

Moreover, the dependent claims further patentably define the claimed subject matter, and are patentable for the features set forth the independent claim as well as for the features recited therein.

Thus, claim 2 further patentably recites that the calcium pyrophosphate is present in an amount of between 3% and 8% by weight of the composition, excluding any coating compositions.

Claim 3 further patentably recites that the gum base constitutes from 10% to 99% by weight of the composition.

Claim 4 further patentably recites that the gum base comprises at least one of the following; natural or synthetic elastomeric compounds, natural or synthetic resin compounds, fillers, softening compounds, antioxidants and colorants.

Claim 5 further patentably recites that the composition is formulated as a confectionary composition in which said confectionary base constitutes from 0% to 99% by weight of the composition.

Claim 6 further patentably recites that the chewing gum or confectionary additives comprise at least one of the following ingredients: sweeteners, high intensity sweeteners, taste enhancers, flavoring agents, and coloring agents.

Claim 7 further patentably recites that the composition is essentially sugar-free.

Claim 8 further patentably recites that the composition comprises at least one additional tooth whitening agent.

Claim 9 further patentably recites that the at least one additional tooth whitening agent is present in between 0.01% and 10.0% by weight of the composition, excluding any coating.

Claim 10 further patentably recites that the at least one additional tooth whitening agent comprises a bicarbonate salt.

Claim 11 further patentably recites that the at least one additional tooth whitening agent comprises sodium bicarbonate, said agent being present in between 0.3% and 0.4% by weight of the composition, excluding any coating.

Claim 12 further patentably recites that the at least one of said additives and said tooth whitening agent is encapsulated.

Claim 13 further patentably recites that the composition further comprise at least one of the following: oral hygiene promoting agents, anti-calculus agents, anti-microbial agents, anti-inflammatory agents, desensitizing agents, therapeutically active agents, and remineralizing agents.

Claim 14 further patentably recites that the composition further comprises a supplement.

Claim 15 further patentably recites that the supplement comprises vitamin C.

Claim 16 further patentably recites that the oral hygiene promoting agent comprises urea, said urea being present in between 0.15% and 25% by weight.

Claim 23 further patentably recites that the calcium pyrophosphate is present in an amount of between 4.5% and 7.5 % by weight of the composition, excluding any coating compositions.

Claim 24 further patentably recites that the calcium pyrophosphate is present in an amount of between 5.5% and 7 % by weight of the composition, excluding any coating compositions.

Claim 25 further patentably recites that the composition is formulated as a chewing gum composition wherein which said gum base constitutes from 15% to 80% by weight of the composition.

Claim 26 further patentably recites that the composition is formulated as a chewing gum composition wherein said gum base constitutes 25% to 60 % by weight of the composition.

Claim 27 further patentably recites that the at least one additional tooth whitening agent is present in between 0.1 and 2.0% by weight of the composition, excluding any coating.

Claim 28 further patentably recites that the at least one additional tooth whitening agent is present in between 0.25% and 1.0% by weight of the composition, excluding any coating.

Claim 29 further patentably recites that the oral hygiene promoting agent comprises urea, said urea being present in between 0.4% and 10% by weight.

Claim 30 further patentably recites that the oral hygiene promoting agent comprises urea, said urea being present in between 0.8% and 5% by weight.

Claim 31 further patentably recites the oral hygiene promoting agent comprises urea, said urea being present in between 1.5 % and 2.5% by weight.

Claim 20 patentably recites a method of whitening tooth surfaces by consuming a solid, oral tooth whitening composition according to claim 1, which method is not taught or suggested in Rajaiah.

Claim 21 patentably recites a method of whitening tooth surfaces by consuming a solid, oral tooth whitening composition according to claim 1, said tooth surfaces being discolored after use of tobacco-related products, which method is not taught or suggested in Rajaiah.

Claim 22 patentably recites a method of whitening tooth surfaces by consuming a solid, oral tooth whitening composition according to claim 1, said tooth surfaces being discolored after use of coffee-related products, which method is not taught or suggested in Rajaiah.

Gibbs is utilized in the rejection of claim 12 solely for assertions that it would have been obvious to encapsulate to arrive at the subject matter recited in claim 12. However, whether or not encapsulation would have been obvious in view of Gibbs, for at least the reasons set forth above, Applicant's claimed subject matter would not be at hand.

Accordingly, the rejections of record should be withdrawn.

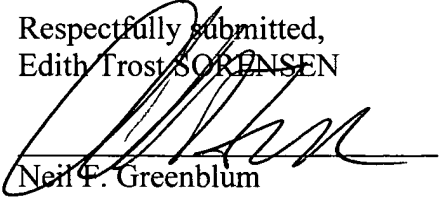
CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

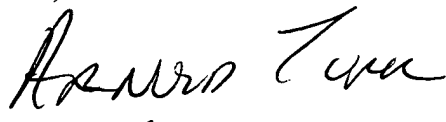
Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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